

Official Title

Identification of elderly patients in need of palliative care by family physicians – the role of palliative care training and the use of a standardized tool (GerPal_ID). A two-phase protocol: randomized trial and prevalence study.

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Abstract

Introduction

In the last decades, the number of people living with chronic diseases had increased, mainly due to the aging of the population. Such chronic, progressive, life threatening and burdening diseases, play an important role in this new era of palliative care.

Despite the growing scientific and social interest in palliative care, there is still a delay in the identification of patients with palliative care needs. This leads to a late integration in a palliative care network and consequent deprivation of the major advantages of an early and progressive integration.

The aim of this study is to evaluate the role of palliative care training and the use of a structured tool, in the identification of the elderly population in need of palliative care by family physicians. And also to conduct a prevalence study to further the knowledge about how many elder people in primary care have the need of a palliative care approach.

Methods and analysis

This study protocol describes a primary care two-phase study. The first phase is designed to assess the role of palliative care training and the use of a structured tool in the accuracy of recognizing patients with palliative care needs by family physicians. A four-arm trial will be conducted to assess which intervention provides a more accurate identification of patients with palliative care needs by family physicians.

In the second phase, once the most accurate identification strategy has been found, a prevalence study will be conducted in Center Healthcare Administrative Region, in order to identify geriatric patients, managed in primary care, who have palliative care needs and try to identify their care need complexity.

Ethics and dissemination

The study will be conducted in accordance with the principles expressed in the Declaration of Helsinki. It has full approval from the Ethics Committee of the Faculty of Health Sciences, University of Beira Interior. Study results will be published in peer-reviewed journals and presented at national and international conferences.

Article Summary

- ◆ The palliative care training program will be structured according GPs' perception about palliative care training needs.
- ◆ Development of a tool to assess accuracy in the identification of geriatric patients with palliative care needs.
- ◆ GPs will be randomized and compared in a four-arm vs control trial to identify the best intervention to assess palliative care needs.
- ◆ The prevalence study will evaluate a representative sample of Health Region of Portugal's geriatric patients.
- ◆ GPs' sample will be a convenience one, evaluating those who already are interested in palliative care.

Introduction

In the last decades, the number of people living with chronic diseases had increased, mainly due to the aging of the population, leading to an increase in dependency status and entailing important social costs.¹

These chronic, progressive, life threatening and burden diseases, play an important role in this new era of Palliative Care (PC) approach.

Most patients with chronic illness are managed in primary care over a long period of time.² General Practitioners (GP), can play an important role in the PC network. When the GP is involved, the provision of PC seems to improve, with benefits for both patients and their families.^{3,4}

Some evidence also show that there is a benefit in an early integration of palliative care, following global patient care in several diseases^{5,6}, although GPs report not having the knowledge and skills to assess unmet needs.^{7,8}

Side by side with PC training, it is increasingly known that systematic identification tools can improve the recognition of patients with PC needs, becoming an important strategy to provide an earlier palliative approach to these patients.^{9,10}

According to a recent review, there are several tools appropriate for primary care use¹¹, and the SPICT™ shows to be one of most suitable for this context.¹²

The prevalence of elderly patients with palliative care needs can go from 8,0-17,3%,^{13,14} according to differences in the population studied and tool used.

It seems to be consonant that knowing the prevalence and characteristics of patients that may be in risk of deteriorating in primary healthcare can help GPs identify such patients earlier, help them to overcome the barriers to initiate end-of-life discussions conducting to a more efficient strategy to achieve each patient's care goals.^{7,13}

Study Objectives

The primary objective of the study described in the protocol is to perform a randomized trial to ascertain if PC training and the use of a structured tool (Portuguese version of SPICT™)¹⁵ can improve GP's correct identification of geriatric patients with palliative care needs.

Specific objectives are to:

- ◆ Perform a Clinical cases base PC training program for GPs, addressing the importance of an efficient identification of geriatric patients managed in primary care.
- ◆ Develop a Clinical Cases Based Tool for Palliative Care Identification (CCB-PCId), to evaluate the accurate identification of patients with palliative care needs
- ◆ Assess whether different training programs and a structured tool can improve GPs awareness to a correct identification of geriatric patients with palliative care needs.
- ◆ Investigate the real prevalence and characteristics of primary care geriatric outpatients, managed in Center Healthcare Administrative Region, with PC needs.

Methods and analysis

Study design

The study consists of two phases:

- ◆ Randomized trial with GPs to determine the role of two different training programs and a structured tool in the identification of geriatric patients with palliative care needs.
- ◆ Cross-sectional, analytical study of the prevalence and patterns of geriatric patients with PC needs, managed in primary care in Portugal's Center Healthcare Administrative Region.

Phase I: the role of a palliative care training program and of a structured tool in the identification of patients with palliative care needs.

Design

Randomized clinical trial

Setting

GPs (fellows and specialists) from Center Healthcare Administrative Region will be invited to take part in the study. Those who accept, will be randomized into four harms (Control group, receiving only a structured tool, receiving standard PC training, receiving clinical cases based PC training). Then, each group will be given the CRB-PCId before and after intervention and the scores will be compared within the group and between groups.

Pre-study procedures

A PC expert panel will take part in two pre-study steps: (i) The PC training program and (ii) the CCB-PCId construction.

The PC training program for primary care

According to the results of two online focus groups with GPs and the PC expert panel, a PC training program for GPs will be built, focusing on the role of GPs in the PC network, the importance and the knowhow about patients with palliative care needs' identification.

CCB-PCId

The PC expert panel will build a tool, clinical record based, to evaluate the accuracy of palliative care needs identification.

This tool will consist of a set of clinical cases from fictitious patients, some of those in need of palliative care and others without, according to the PC expert panel.

The accuracy's pre and after intervention, will be measured and compared to evaluate differences within group and between groups of the randomized trial.

Sample size

From the bibliographic research, it was not possible to infer the expected behavior in each group. Thus, the sample was calculated according to the Cohen Tables ¹⁶, for a four-harm comparison, with analysis of dichotomous variables, with a test power of 80% and a significance of 0.05. A total of 45 GPs was obtained per group, making up a minimum sample of 180.

Study procedures

This phase of the study is expected to start in September 2019.

The GPs (fellows and specialists) from Center Healthcare Administrative Region will be invited to take part in this trial. The invitations will be conducted with the help of the Center Healthcare Administrative Region and by spreading the invitation in some general practice professionals' mailing lists and online platforms.

First, GPs will be contacted and those who accept to participate will be randomized into one of the four-harm study groups – 1. Control Group, 2. Identification tool group, 3. Standard PC training (defined as a standard PC training model used in Center Healthcare Administrative Region) , 4 – Clinical cases based PC training.

Standardization will be performed so that GPs randomization take into account the different inner sample characteristics.

Then, each group will be asked to perform CCB-PCId before and after completing the group intervention:

- ◆ *Control Group* – no intervention;
- ◆ *Identification tool group* – before and after getting the SPICT^{PT} and a short explanation on how to use it;
- ◆ *Standard PC training group* – before and after training program;
- ◆ *Clinical cases based PC training group* – before and after training program;

The accuracy on the identification before and after intervention will be compared within each group and between the four groups, to determine which study harm is the most accurate one.

Data collection

The main investigator will be responsible to store the data collected during the trial.

Besides the main outcome of this phase is to determine which intervention provides the most accurate identification, to control some confusing variables, it will be collected some demographic data, such as age, sex, place of work, work experience (years) and previous training in PC.

Data will be electronically stored in a database specifically designed for this study. Data will be encrypted and password protected. Information will be treated in strict confidentiality to protect the privacy of GPs. Paper copies of all informed consents will be retained in a locked file, separate from any study data.

Statistical analysis

A descriptive analysis will be performed to all study variables, namely the number of valid observations, mean, SD, median and range for quantitative variables and absolute and relative frequencies for qualitative variables whenever it will be considered adequate.

According to previous reports ^{13,17}, patients with palliative care needs will be defined as ≥ 2 positive general indicators or ≥ 1 positive disease-specific indicators in the SPICT^{PT}.

Comparisons between two or more independent groups of quantitative variables will be performed using Pearson's χ^2 test or Fisher's exact test, analysis of variance (ANOVA) or non-parametric Kruskal-Wallis test. All tests will be two-sided using a significance level of 0.05. Statistical analysis will be conducted using SPSS V.24.0 or higher.

Phase II: prevalence of palliative care needs and care need complexity among geriatric patients managed in primary care in the Center Healthcare Administrative Region – Portugal

Design

Cross-sectional, analytical study.

Setting

GPs from Centre Healthcare Administrative Region, that accepted to participate in phase I, will be asked to screen geriatric patients in their files to determine the prevalence of geriatric patients with PC needs and their care need complexity in Centre Healthcare Administrative Region.

Sample size

According to Center Healthcare Administrative Region's Local health profile 2017¹⁸, there are 402471 individuals aged 65 or more. This value was assumed as these individuals were all managed in primary care to maximize the sample size.

Since the prevalence of geriatric patients managed in primary care with palliative care needs varies greatly across research literature, a prevalence of 50% was assumed in order to maximize the sample size. For the study to be able to estimate a 95% CI for the prevalence of geriatric patients managed in primary care with palliative care needs with a maximum precision error of 2.5%, a total of 1531 patients should be screened.

To safeguard a 30% dropout rate, each of the 180 GPs will be asked to evaluate at least 13 of their clinical files' managed geriatric patients. This data may be recalculated according to the phase I sample dropout, always granting the minimal required sample size.

Study procedures

According to phase I results, the most accurate intervention will be available to all GPs, to maximize their identification's capacity.

Then, all GPs recruited will be asked to participate in a cross-sectional, analytical study with three aims:

- ◆ Determine the prevalence of geriatric patients with palliative care needs managed in primary care in Center Healthcare Administrative Region;
- ◆ Determine these patients care need complexity applying a translated version of IDC-Pal¹⁹;
- ◆ Determine demographic and clinical characteristics of these patients.

Each GP will be asked to evaluate at least 9 patients from his clinical file, according to a convenience sample built with patients undergoing for a medical evaluation during a determined period.

Patients willing to participate in the study must give written informed consent and present willingness and ability to comply with the study requirements. Participants will be excluded if they are acutely unwell or refuse to participate. Every patient aged above 65 years old, accepting to participate, will be admitted for screening.

Data collection

GPs will be responsible for collecting all data about each patient during their consultations and through the completion of a paper questionnaire developed specifically for this study.

The geriatric patients' palliative care needs will be assessed using the knowledge of GPs enrolled (attending they have all received PC training program) and using the SPICT^{PT} according to phase I defined parameters.

The patients' care need complexity will be screened according to ICD-Pal translated tool results. This screening will only be conducted to patients with positive palliative care needs screening.

Patients' demographic and clinical characteristics as age, sex, residence area, living situation, main underlying disease and current care services will also be recorded.

Data will be electronically stored in a database specifically designed for this study. Data will be encrypted and password protected. Information will be treated in strict confidentiality to protect the privacy of patients. Paper copies of all informed consents will be retained in a locked file, separate from any study data.

Statistical analysis

A descriptive analysis will be performed to all study variables, namely the number of valid observations, mean, SD, median and range for quantitative variables and absolute and relative frequencies for qualitative variables whenever it will be considered adequate.

Prevalence of geriatric patients with PC needs will be calculated together with corresponding 95% CI.

Moreover, the prevalence of geriatric patients with PC needs will be estimated by subgroups, namely gender, age, residence area, main underlying disease and current care services.

Univariate analysis will be conducted to study the associations between those characteristics and PC needs using χ^2 test (qualitative characteristics) or T test/Mann-Whitney (quantitative characteristics).

All tests will be two-sided using a significance level of 0.05. Statistical analysis will be conducted using SPSS V.24.0 or higher.

Ethics and dissemination

The study will be conducted in accordance with the principles expressed in the Declaration of Helsinki. It has full approval from the Ethics Committee of the Faculty of Health Sciences, University of Beira Interior. Study results will be published in peer-reviewed journals and presented at national and international conferences.

References

1. Prince, M. J. *et al.* The burden of disease in older people and implications for health policy and practice. *Lancet* **385**, 549–562 (2015).
2. Downing, J. *et al.* Promoting palliative care in the community: Production of the primary palliative care toolkit by the European Association of Palliative Care Taskforce in primary palliative care. *Palliat. Med.* **29**, 101–111 (2014).
3. Mitchell, G. K. How well do general practitioners deliver palliative care? A systematic review. *Palliat. Med.* **16**, 457–464 (2002).
4. McWhinney, I. R. & Stewart, M. A. Home care of dying patients. Family physicians' experience with a palliative care support team. *Can Fam Physician* **40**, 240–246 (1994).
5. Morrison, R. S. *et al.* The care span: Palliative care consultation teams cut hospital costs for Medicaid beneficiaries. *Health Aff.* **30**, 454–463 (2011).
6. Hall, S., Davies, E., Frogatt, K., Higginson, I. & Kolliakou, A. Interventions for improving palliative care for older people living in nursing care homes. *Cochrane Database Syst. Rev.* (2008). doi:10.1002/14651858.CD007132.pub2. www.cochranelibrary.com
7. De Korte-Verhoef, M. C. *et al.* General practitioners' perspectives on the avoidability of hospitalizations at the end of life: A mixed-method study. *Palliat. Med.* **28**, 949–958 (2014).
8. Devroey, D. *et al.* Is There a Need for Early Palliative Care in Patients With Life-Limiting Illnesses? Interview Study With Patients About Experienced Care Needs From Diagnosis Onward. *Am. J. Hosp. Palliat. Med.* **33**, 489–497 (2015).
9. K, T. Using prognostic indicator guidance to plan care for final stages of life. *Prim. Heal. Care* **6**, 25–28 (2010).
10. Abarshi, E. A. *et al.* Recognising patients who will die in the near future: A nationwide study via the Dutch Sentinel Network of GPs. *Br. J. Gen. Pract.* **61**, 371–378 (2011).
11. Maas, E. A. T., Murray, S. A., Engels, Y. & Campbell, C. What tools are available to identify patients with palliative care needs in primary care: A systematic literature review and survey of European practice. *BMJ Support. Palliat. Care* **3**, 444–451 (2013).
12. Walsh, R. I., Mitchell, G., Francis, L. & Driel, M. L. Van. current review what Diagnostic tools exist for the early identification of Palliative care Patients in General Practice ? A systematic review. 118–123 (2010).
13. Hamano, J., Oishi, A. & Kizawa, Y. Prevalence and Characteristics of Patients Being at Risk of Deteriorating and Dying in Primary Care. *J. Pain Symptom Manage.* **57**, 266–272.e1 (2019).
14. Constante, C. *et al.* Prevalence and characteristics of patients with advanced chronic conditions in need of palliative care in the general population: A cross-sectional study. *Palliat. Med.* **28**, 302–311 (2014).
15. Highet, G., Crawford, D., Murray, S. A. & Boyd, K. Development and evaluation of the supportive and palliative care indicators tool (SPICT): A mixed-methods study. *BMJ Support. Palliat. Care* **4**, 285–290 (2014).
16. Cohen, J. A Power Primer. (1992).
17. Hamano, J., Oishi, A. & Kizawa, Y. Identified Palliative Care Approach Needs with SPICT in Family Practice: A Preliminary Observational Study. *J. Palliat. Med.* **21**, 992–998 (2018).
18. Pimentel, J. P., Durval, M., Araújo, F. O. & Guerreiro, A. C. ACeS Baixo Mondego. (2017).
19. Martin Rosello ML, Fernandez Lopez A, Sanz-Amores R, et al. Instrument Diagnosing Complexity in Palliative Care, IDC-Pal. Junta Andalucía Cons Igualdad, Salud y Políticas Soc

[Internet] 2014. Available from:
http://www.juntadeandalucia.es/salud/export/sites/csalud/galerias/documentos/p_3_p_3_procesos_asistenciales_integrados/cuidados_paliativos/idc_pal_2014.pdf.
[Accessed 6 April 2019].

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